# Adding remote ultrasound "knobology" control to remote just-in-time telementored trauma ultrasound: a randomised controlled trial

analysis plan
participant data

## Plain English summary of protocol

Background and study aims

Traumatic injury remains the leading cause of potentially preventable death in the Western world, especially in the Arctic, and is one, if not the most feared, pathology in Space Medicine. Resuscitative ultrasound is becoming a universal tool in emergency medicine that can capture a vast array of injuries and deranged physiology in the critically injured. An unfortunate practical reality however, is that ultrasound is very user dependant. Space Medicine has led the innovation however, in using advanced telecommunications to allow experts not at the scene of the trauma (remote expert) to guide non-experts to use on-scene ultrasound equipment to get clinically meaningful images. Furthermore, the Trauma Services group at the University of Calgary has led the world in examining the use of this technology in a clinical setting on earth. The Ultrasonix Corporation, under contract to the Canadian Space Agency (CSA), has developed an advanced Graphic User Interface (GUI) which allows a expert to control the ultrasound settings of a Ultrasonix Ultrasound remotely and to communicate with the non-expert user over a unique voice and video connection. A consistent finding of this experience has been the sentiment that being able to transfer the responsibility of controlling the ultrasound settings (knobology) from the on-site inexperienced user to the remote expert. The aim of this study is to test whether the use of a remote controlled GUI improve the usefulness of emergency "just-intime" remote telementored ultrasound as measured by examining the accuracy of the examination

## Who can participate?

Firefighters from the city of Edmonton that have not had any prior experience with trauma ultrasound.

## What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 perform a telementored ultrasound examination on an ultrasound phantom (a training model that gives realistic ultrasound images when scanned) to which fluid has been added. Those in group 2 perform a telementored ultrasound examination on an ultrasound phantom to which fluid has not been added. All participants are mentored by remote ultrasound experts who can view their

hand movements and provide 2-way communication. The intervention being randomized is the remote control of the ultrasound machine "knobology" by the remote mentor or not which is randomly assigned. The accuracy of the mentored examination is determined by the known "truth" regarding the volume of fluid added to the phantom. The time needed to complete the examination is also recorded with and without GUI assistance. All volunteers and remote mentors are asked to complete questionnaires for each examination in which all responses will be anonymous, regarding how useful they found the technique and the GUI, any suggested modifications to the GUI, and other general comments.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? Foothills Medical Centre, Calgary (Canada)

When is the study starting and how long is it expected to run for? October 2014 to March 2015

Who is funding the study? Canadian Space Agency

Who is the main contact?
Professor Andrew Kirkpatrick
andrew.kirkpatrick@albertahealthservices.ca

# **Contact information**

## Type(s)

Scientific

#### Contact name

Dr Andrew Kirkpatrick

#### Contact details

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## Additional identifiers

Protocol serial number 20949

# Study information

Scientific Title

Medical ultrasound remote access/control interface testing requirements for a graphic user interface (GUI)

## **Study objectives**

The aim is to test the usefulness of a remote ultrasound examination that utilizes a graphic user interface to assist with the knobology of the remote ultrasound machine.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

University of Calgary Office of Medical Bioethics, 06/07/2007, ref: 20949

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Diagnostic

## Health condition(s) or problem(s) studied

Trauma Resuscitation

#### **Interventions**

Pre-hospital responders unfamiliar with trauma ultrasound will be randomized to perform a telementored ultrasound examination on an ultrasound phantom to which fluid has been randomly added or not. They will be mentored by remote ultrasound experts who can view their hand movements and provide 2-way communication. The intervention being randomized is the remote control of the ultrasound machine "knobology" by the remote mentor or not which will be randomly assigned

#### Intervention Type

Device

#### Phase

Not Applicable

## Primary outcome(s)

The accuracy of the mentored examination to detect any free fluid within the phantom (Binary yes/no determination) with and without GUI assistance.

## Key secondary outcome(s))

The relative user satisfaction will be assessed using a previously verified post-examination satisfaction survey with the Likert scores compared for those using the GUI versus not.

## Completion date

30/03/2015

# **Eligibility**

## Key inclusion criteria

- 1. Pre-hospital care provider
- 2. Willingness to participate
- 3. Command of English

## Participant type(s)

Health professional

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

All

#### Total final enrolment

101

## Key exclusion criteria

- 1. Any prior experience with ultrasound
- 2. Unwilling to participate
- 3. Unable to speak English

#### Date of first enrolment

29/10/2014

## Date of final enrolment

30/05/2015

## Locations

## Countries of recruitment

Canada

# Study participating centre Foothills Medical Centre

Trauma Services 1403 29 St NW Calgary Canada T2N 2T9

# Sponsor information

#### Organisation

Canadian Space Agency

#### **ROR**

https://ror.org/03a1gte98

# Funder(s)

## Funder type

Government

#### **Funder Name**

Canadian Space Agency

#### Alternative Name(s)

Agence Spatiale Canadienne, The Canadian Space Agency (CSA), L'Agence spatiale canadienne (ASC), Government of Canada, Canadian Space Agency, csa asc, canadianspaceagency, CSA, ASC

## **Funding Body Type**

Government organisation

## Funding Body Subtype

National government

#### Location

Canada

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016	25/06/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes